AMENDED CLAIMS

[received by the International Bureau on 20 October 1998 (20.10.98); original claims 1,2,4,10,11 and 13 amended; remaining claims unchanged (2 pages)]

1. A pharmaceutical excipient useful in the formulation of dry powder inhaler compositions, characterized in that it comprises a particulate roller-dried anhydrous β-lactose.

2. An excipient according to claim 1, characterized in that the roller-dried anhydrous β-lactose particles have a size between 50 and 250 micrometers.

3. An excipient according to claim 2, characterized in that said particles have a size comprised between 100 and 160 micrometers.

4. An excipient according to any of claims 1 to 3, characterized in that said particulate roller-dried anhydrous β-lactose has a rugosity comprised between 1.9 and 2.4.

5. A dry powder inhaler pharmaceutical composition, characterized in that it comprises a mixture of an active ingredient and an excipient as claimed in any one of claims 1 to 4.

6. A composition according to claim 5, characterized in that the active ingredient is a particulate solid with a particle diameter comprised between 0.5 and 6 micrometers.

7. A composition according to either of claims 5 and 6, characterized in that the weight ratio of the active ingredient in relation to the excipient is of from 0.1/100 to 50/100.

8. A composition according to any of claims 5 to 7, characterized in that the active ingredient is selected from the group comprising mucolytics, steroids, sympathomimetics, proteins, peptides and inhibitors of mediator's release.

9. A composition according to claim 8, characterized in that the active ingredient is a mucolytic agent such as L-lysine N-acetylcysteinate.

10. A composition according to claim 9, characterized in that it comprises a mixture of particulate L-lysine N-acetylcysteinate and

roller-dried anhydrous β-lactose constituted by particles of 100 to 160 micrometers in size and of 1.9 to 2.4 in rugosity, the weight ratio of L-lysine N-acetylcysteinate in relation to the roller-dried anhydrous β-lactose being of from 1/2 to 1/6.

11. A composition according to claim 9, characterized in that the weight ratio of L-lysine N-acéthylcysteinate in relation to the roller-dried anhydrous β-lactose is comprised between 1/2 and 1/4.

12. A composition according to claim 11, characterized in that said weight ratio is of the order of 1/4.

13. A process for the preparation of an excipient as claimed in any one of claims 1 to 4, characterized in that anhydrous β-lactose in a powder form is dissolved in demineralised water, fed between two counterrotating drums, which are steam heated and then screeped from the surface of the drums.